

For VOLUNTARY reporting

Fax to 1-800-FDA-0178 Or mail to address on back

Form approved: OMB	No. See OMB statement on reverse
FDA Use Only	ese emb statement en reverse
Triage unit sequence #	

	L PRODUCTS REPORTING	J PROGRAM	Page	_ or		<u> </u>						
A. Patient in		3. Sex 4. Weight	5 Height	C. Suspect pi		•		ons that a	pply)			
. Fatient ID	2. Age at time of event or Date of birth:	3. Sex 4. Weight	t 5. Height	a.	ide strengti i	anu uosay	3 IOIIII)					
			kg 🗌 in 🗌 cm	b.								
B. ■ Advers	se event and/or	■ Product proble	em (see back)	2. Generic name (or	r ingradiants)	or type of	dovice					
	t, patient outcome	disability		a.	ingredients)	or type or	uevice					
(check all that a	ppiy)	congenital anomaly		b								
(mo/day/yr) — required intervention to prevent										.,		
☐ life-threateni	on – initial or prolonged	permanent impairme	ŭ	3. Dose, route & free	quency used		from/to (c	or best estim		ant/explant dates)		
nospitalizatio	on – initial of prolonged	none of the above (e	xpiairi iri 63)	a. 			a. 					
3. Describe event or problem		4. Date of event		b.		l l	O.					
				5. Diagnosis for use	(indication)			6. Exp.	date	7. Product is		
DRAFT: 1 (Do not use f				a.				a.		a. OTC		
				b.				b.		b. RX		
		.00		8. Event abated afte	r uso	0 Event	roappoare	nd after	10.11	Se of device		
		14 190	100	stopped or dose	reduced?	reintro	reappeare duction?	u aitei	a. [initial reuse		
	11	الا [8]	tinyı	a. yes no n	/a unk	a. 🗌 y	es no	n/a		unknown		
	anfl: "	iono,		b. yes no n	/a □unk	b. 🗌 y	es no	n/a	b.	☐ initial ☐ reuse ☐ unknown		
n	KM, co	14 LOH		11. Product #(s) (fill i	in those that	apply)						
	ISP.	"			a.		1		b.			
40	ut Nage			lot #			- —					
ma P	, U •			NDC #								
IDO				model #								
•				catalog #								
				serial #								
				other #			-					
5. Relevant tests/	laboratory data, including	dates			nealth orofessional	lay use patien	er/	other:				
				13. Product available	e for evaluat	ion? (do n	ot send to	FDA) 14.	Labe	l available?		
		a. yes no returned to manufacturer on				a.	(see back) a. □ ves □ no □ unk					
					b yes no returned to manufacturer on							
			15. Manufacturer name and address				16. Dire	16. Directions for use (see back)				
				a.				a.	back)			
6. Other relevant	history, including preexis	ing medical conditions	(e.g., race,	u.				l u.				
allergies, pregna	ancy, smoking and alcohol u	ise, hepatic/renal dysfunc	tion, etc.)	b.				b.				
				D. Reporter (s	ee confident	tiality sect	ion on bac	ck)				
				1. Name, address		(optional:	email/fax)	2. Pho	ne nui	mber		
								3 Date	of th	is report		
								J. Date	; 01 111	is report		
	edical products (including	dietary supplements) and	therapy dates					4. Hea	Ith pro	ofessional?		
(exclude treatment of event)							□ 3	yes [_ no			
								5 Occ	upatio	on/specialty		
				6. Attachments	7. Follow	-up repor	t? ges	no	8. A	Also reported to		
				included?	FDA ref#					manufacturer		
						ity disclos	ed to		- [medical facility		
				If you do not war the manufacturer	r, place an ")	X" in this I	ox.			distributor		

ADVICE ABOUT VOLUNTARY REPORTING

(For a complete set of instructions or to report via internet, visit the MedWatch Homepage: www.fda.gov/medwatch)

Report experiences with:

- medications (drugs or biologics, excluding vaccines)
- · medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- cosmetics

If event involves a vaccine, it should be reported to the Vaccine Adverse Event Reporting System (VAERS) on form VAERS-1, available by calling 1-800-822-7967.

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- · disability (significant, persistent or permanent)
- · congenital anomaly
- required intervention to prevent permanent impairment or damage

Report serious adverse events even if:

- you're not certain the product caused the event
- you don't have all the details

Report product/use problems – quality, performance or safety concerns such as:

- · suspected contamination
- questionable stability
- · defective components
- · device malfunctions
- · therapeutic failures
- product confusion (caused by name, labeling, design, or packaging)

How to report:

- · just fill in the sections that apply to your report
- attach additional pages if needed and check yes box in block D6
- use a separate form for each patient

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-1088 to report by phone or for a copy

of a complete set of instructions

Note:

- **Block C14** If reporting on a drug product problem or on a special nutritional, please attach labeling/ packaging, if available, and check *yes* in block D6.
- Block C16 Applicable to special nutritionals only; please provide directions for use as listed on the product label.

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise, by checking Block D9. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Office Paperwork Reduction Project (0910-0291) Hubert H. Humphrey Building, Room 531-H 200 Independence Avenue, S.W. Washington, DC 20201

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." Please do NOT return this form to this address.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

FDA Form 3500-back

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services

Public Health Service Food and Drug Administration Rockville, MD 20857

Official Business
Penalty for Private Use \$300

BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION



The FDA Medical Products Reporting Program Food and Drug Administration 5600 Fishers Lane Rockville, MD 20852-9787



